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| **National CAR T Clinical Panel for lymphoma Application Form:** **Tecartus for treating mantle cell lymphoma (MCL) in adults previously treated with two or more lines of systemic therapy** Forms must be submitted to england.nccp@nhs.net by 5pm each Friday for consideration at the NCCP lymphoma on the following Tuesday |

**NOTES FOR COMPLETION**

Section A

* This section must be completed by the treating consultant at the patient’s local hospital and should provide a comprehensive history of the patient’s treatment to date
* Reviewing centres should countersign this section to confirm the patient is eligible for consideration for CAR T therapy

SECTION B

* This section must be completed by a CAR T centre following a consultation with the patient

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| **SECTION A** |
| **Patient details** |
| Name |  |
| NHS No |  |
| Age | *Must be 18 years or older on date of approval by National CAR T Clinical Panel* |
| **Clinical background** |
| Referral details | Consultant name:Hospital: Date of referral for consideration for CAR T: |
| 1. Confirmed histological diagnosis
 | *Delete as appropriate** Mantle cell lymphoma with cyclin D1 overexpression
* Mantle cell lymphoma with the presence of the translocation t(11:14)
 |
| 1. Please provide an overview of the patient’s previous treatment
 | *(please include number of lines of treatment, regimen details and date of last therapy)* *Note:** *Radiotherapy is not counted as a line of treatment*
* *Corticosteroids alone are not counted as a line of treatment*
* *Stem cell transplant is not counted as a line of treatment when used as consolidation of a response to first or second line therapy*

***Please provide a narrative of the patient’s treatment to date:***

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| --- | --- | --- | --- | --- |
| Treatment regimen  | Start date | Stop date | Number of cycles | Response to treatment |
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*If current treatment is ongoing write ‘ongoing’ under ‘response to treatment’* |
| 1. The histological diagnosis of MCL has been either made by or reviewed and confirmed by a designated lymphoma stem cell transplant centre
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| Biopsy number | Date performed | Conclusion from report |
|  |  |  |
| 1st |  |  |
| 2nd |  |  |
| 3rd |  |  |
| Most recent (if not one of above) |  |  |

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| 1. I confirm that the patient fulfils one of the following clinical scenarios relating to the definition of relapsed or refractory lymphoma
 | **Refractory disease is defined as either progressive disease as the best response to the last line of systemic therapy or stable disease as the best response after at least 2 cycles of the last line of therapy with stable disease duration lasting no longer than 6 months from the last dose of the last line of systemic therapy.** **Relapsed disease is defined as disease that responded partially or completely to the last line of therapy and has since progressed.****Progressive disease must be defined radiologically as per RECIST version 1.1 and be based on CT or MR scans. Progressive disease cannot be defined on just an increased SUV on a PET scan; in such a circumstance, RECIST version 1.1 criteria for progressive disease must be met.****Neither radiotherapy nor steroids can be counted as a line of therapy.**The patient (delete as appropriate): * has received 2 or more lines of systemic therapy for MCL and was refractory to the last line of systemic therapy OR
* has received 2 or more lines of systemic therapy for MCL and relapsed after the last line of systemic therapy
 |
| 1. I confirm that that the patient has been previously treated for MCL with one of the following cytotoxic chemotherapy regimens: an anthracycline-containing regimen or a bendamustine-containing regimen or a regimen containing high dose cytarabine with or without cisplatin/carboplatin
 | The patient (delete as appropriate): * has been previously treated with an anthracycline-containing regimen OR
* has been previously treated with a bendamustine-containing regimen OR
* has been previously treated with a high dose cytarabine-containing regimen with or without cisplatin/carboplatin
 |
| 1. I confirm that that the patient has been previously treated for MCL with a BTK inhibitor (such as ibrutinib or acalabrutinib) and that the patient progressed either during treatment or following discontinuation of the BTK inhibitor.
 | The patient (delete as appropriate): * has been previously treated with ibrutinib OR
* has been previously treated with acalabrutinib OR
* has been previously treated with another BTK inhibitor
 |
| 1. I confirm that the patient has been previously treated with at least one anti-CD20 monoclonal antibody unless there is clear documentation of the determination of CD20 negative disease
 |  |
| 1. Please provide details on the patient’s prior treatment with stem cell transplantation (SCT)
 | The patient (delete as appropriate):* has not had SCT
* has had autologous SCT
* has had allogeneic SCT
 |
| 1. I confirm that either the patient has not previously been treated with an anti-CD19 antibody-drug conjugate or if previously treated with an anti-CD19 antibody-drug conjugate that a biopsy of the relapsed/refractory disease has been done and has been shown to be CD19 positive
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| 1. I confirm that the patient does not have known active CNS involvement by the lymphoma
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| 1. I confirm that the patient has an ECOG performance score of 0 or 1
 | *Please select from the options below*

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| **Grade** | **ECOG performance status** |  |
| 0 | Fully active, able to carry on all pre-disease performance without restriction |  |
| 1 | Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work |  |
| 2 | Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours |  |
| 3 | Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours |  |
| 4 | Completely disabled; cannot carry on any selfcare; totally confined to bed or chair |  |

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| 1. Please provide details of any active co-morbidities
 | Please list all active co-morbidities

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| *Active co-morbidity* | *Severity score (see score under table)* |
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*1: Current mild problem or past significant problem. 2: Moderate disability or morbidity and/or requires therapy. 3: Severe problem and/or constant and significant disability and/or hard to control chronic problems. 4: Extremely severe problem and/or immediate treatment required and/or organ failure and/or severe functional impairment.* |
| **Allogeneic centre review (if applicable)** |
| 1. I confirm that the patient has sufficient end organ function to tolerate treatment with CAR T cell therapy
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| 1. I confirm that the patient has either had no previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy or the patient has been treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial.
 | (delete as appropriate)* No previous therapy with any genetically modified autologous or allogeneic T cell immunotherapy **or**
* Previously treated with doses of genetically modified autologous or allogeneic T cell immunotherapy within an abandoned dosing cohort in a first in human dose-escalation phase I clinical trial
 |
| 1. I confirm that this patient should be referred to a CAR T centre for consideration for CAR T Therapy
 | *Please specify** Patient is clearly eligible and has been forwarded to a CAR T centre for consideration without review.
* Patient reviewed and deemed eligible by autograft centre clinician. Eligibility required confirmation by CAR T centre

Name:Signature:Hospital:Date: |

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| **SECTION B** |
| **Details of consultation at CAR T Centre** |
| Date of consultation  |  |
| Consultant seen |  |
| CAR T Centre |  |
| 1. I confirm that the patient has an ECOG performance score of 0 or 1
 |

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| --- | --- | --- |
| **Grade** | **ECOG performance status** |  |
| 0 | Fully active, able to carry on all pre-disease performance without restriction |  |
| 1 | Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work |  |
| 2 | Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours |  |
| 3 | Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours |  |
| 4 | Completely disabled; cannot carry on any selfcare; totally confined to bed or chair |  |

Please select from the below |
| 1. Prior to infusion 4 doses of tocilizumab are available for use in this patient in the event of the development of cytokine release syndrome
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| **Available clinical trials** |
| 1. List the clinical trials available to this patient
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| **CAR T centre endorsement** |
| I confirm that I endorse this application for treatment | Name:Position: |